CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail,
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June 10, 2005
Date of Deposit

Vita G. Conforti Reg. No. 39,639
Name of Applicant, Assignee or Registered Representative

Signature

June 10, 2005
Date of Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Francisco *et al.*		
Serial No.: 09/724,406		Group Art Unit: 1642
Filed: November 28, 2000		Examiner: Yu, Misook
For:	RECOMBINANT ANTI-CD30 ANTIBODIES AND USES THEREOF	

AFFIDAVIT OF DR. PHILIP TSAI
UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, PHILIP TSAI, do declare and state that:

1. I am a citizen of the United States residing at 22219 NE 159th St., Woodinville, WA 98077.
2. From January 13, 2003 to the present, I have been employed by Seattle Genetics, Inc., assignee of the above identified application, initially as Associate Director, Bioprocess Development from January 13, 2003 to March 16, 2004 and presently as Director, Bioprocess Development from March 16, 2004. I received the degree of Bachelor of Science from University of Illinois, Urbana Champaign, IL in

Chemical Engineering in 1990 and my Ph.D. from California Institute of Technology, Pasadena, CA, in Chemical Engineering in 1995.

3. My academic and technical experience and honors, and a list of my publications are set forth in my curriculum vitae, attached hereto as Exhibit 1.

4. As Director of Bioprocess Development at Seattle Genetics, Inc., I am responsible for maintaining and have oversight of the hybridoma which produces the monoclonal antibody AC10.

5. The hybridoma which produces the monoclonal antibody AC10 has been in the possession and control of Seattle Genetics, Inc. at least since the filing date of the present application, November 28, 2000.

6. The original seed bank received for the hybridoma which produces the monoclonal antibody AC10 was maintained and from that a working seed bank was prepared.

7. Under my direction and control, the working seed bank for monoclonal antibody AC10 was prepared to the requirements for deposit with the ATCC.

8. Under my direction and control, the hybridoma which produces monoclonal antibody AC10 was deposited with the ATCC.

9. The monoclonal antibody AC10 described in the specification as filed on November 28, 2000 is the same as that deposited with the ATCC on April 26, 2005 pursuant to the terms of the Budapest Treaty on the international recognition of the deposit of microorganisms for purposes of patent procedure. The ATCC is located at 10801 University Boulevard, Manassas, Va. 20110-2209, USA.

10. The deposited material deposited as mAC10 hybridoma in the ATCC as PTA-6679 on April 26, 2005 is identical to the biological material, monoclonal antibody AC10, described in the specification.

11. The biological material, monoclonal antibody AC10, described in the specification was in the possession of Seattle Genetics, Inc. at least as of the date the application was filed on November 28, 2000.

12. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 5/26/05

Philip Tsai

Attachments:

Exhibit 1: Curriculum Vitae of Philip Tsai

Philip Tsai
22219 NE 159th St
Woodinville, WA 98077

425 844 8035 (home)
978 902 2225 (cell)
ptsai@seagen.com

Philip S. Tsai

Employment History

March 2004–Present Seattle Genetics, Inc Bothell, WA
Director, BioProcess Development

Jan. 2003–Mar. 2004 Seattle Genetics, Inc Bothell, WA
Associate Director, BioProcess Development

Dec. 2002 Biogen, Inc Cambridge, MA
Senior Development Engineer, Biopharmaceutical Process Sciences

2000–2002 Biogen, Inc Cambridge, MA
Process Engineer II, Biopharmaceutical Process Sciences

1995–1999 Biogen, Inc Cambridge, MA
Process Engineer I, Biopharmaceutical Process Sciences

Education

1992–1995 California Institute of Technology Pasadena, CA
- *Ph.D., Chemical Engineering with Minor in Biology*

1990–1992 California Institute of Technology Pasadena, CA
- *M.S., Chemical Engineering*

1986–1990 University of Illinois Urbana-Champaign, IL
- *B.S., Chemical Engineering*

Experience

Process Development
- Developed CHO and NS0 cell culture processes with objectives of enhancing titer, removing bovine-derived components, and/or preserving product quality attributes for different phases of clinical studies and post market improvement.

Team Leadership
- Lead CMC teams to complete development cycles from process development to cGMP manufacturing to IND submission.

Technology Transfer
- Transferred several developed CHO and NS0 mfg processes into 2000L and 3000L-scale manufacturing facilities and oversaw successful completion of manufacturing campaigns.

Process Validation
- Authored and executed cell culture process consistency validation protocols to support BLA.

Contract PD/Manufacturing
- Transferred two manufacturing processes into contract facilities and provided on-site technical assistance. Participated in evaluation and selection of contract manufacturer for gene therapy program. Oversaw initial adenovirus production bioreactor development.

Business Due Diligence
- Represented Product Development on Due Diligence team to evaluate in-licensing opportunity. Provided recommendations to the

company on strengths and weaknesses.

Technical Innovation

- Developed a chemically defined cell culture media formulation to support growth and production of recombinant CHO cells. The medium is now part of the platform technology used at Biogen.

Regulatory Support

- Authored process development and manufacturing sections of the CMC on multiple IND submissions.

Personnel Development

- Currently managing ten employees with varying experience and background (BS, MS, and Ph.D-level in Chem. Eng. and biological sciences with 10+ yrs of experience).

Publications

P. S. Tsai (2001) Development of a Cell Culture Process for Early Phase Clinical Studies. IBC: Transitions Bench to Clinics. August 2001, Boston, MA.

P. S. Tsai, V. Hatzimanikatis, and J. E. Bailey (1996) Effect of *Vitreoscilla* Hemoglobin Dosage on Microaerobic *Escherichia coli* Carbon and Energy Metabolism. *Biotechnology and Bioengineering*, **49**: 139-150.

J. E. Bailey, P. T. Kallio, P. S. Tsai (1996) Expression of *Vitreoscilla* Hemoglobin is Superior to Horse Heart Myoglobin or Yeast Flavohaemoglobin Expression for Enhancing *Escherichia coli* Growth in a Microaerobic Bioreactor, *Biotechnology Progress*, **12** (6): 751-757.

P. S. Tsai, P. T. Kallio, and J. E. Bailey (1995) Fnr, A Global Transcriptional Regulator of *Escherichia coli*, Activates the *Vitreoscilla* Hemoglobin (VHb) Promoter and Intracellular VHb Expression Increases Cytochrome *d* Promoter Activity, *Biotechnology Progress*, **11**: 288–293.

P. S. Tsai, G. Rao, J. E. Bailey (1995) Improvement of *Escherichia coli* Microaerobic Oxygen Metabolism by *Vitreoscilla* Hemoglobin: New Insights from Culture Fluorescence and Redox Potential, *Biotechnology and Bioengineering*, **47**: 347-354.

P. T. Kallio, D. J. Kim, P. S. Tsai, and J. E. Bailey (1994) Intracellular Expression of *Vitreoscilla* Hemoglobin Alters *Escherichia coli* Energy Metabolism Under Oxygen-limited conditions, *European Journal of Biochemistry*, **219**: 201-208.

P. S. Tsai, M. Naegeli, J. E. Bailey (1994) The Amount and Activity of *Escherichia coli* Cytochrome *o* Are Enhanced by *Vitreoscilla* Hemoglobin Under Microaerobic Conditions, 207th American Chemical Society National Meeting, March 13-17, 1994, San Diego, CA.